

# **Compliance Policy Guide**

## **Guidance for FDA and CBP Staff**

### **Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

Comments and suggestions regarding this Compliance Policy Guide (CPG) should be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with docket number 2003D-0554.

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U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Center for Food Safety and Applied Nutrition  
Center for Veterinary Medicine

Department of Homeland Security  
U.S. Customs and Border Protection

Issued December 2003  
Revised June 2004, August 2004, and November 2004

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# **Compliance Policy Guide**

## **Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

This guidance document represents the Food and Drug Administration's (FDA) and Customs and Border Protection's (CBP) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA, CBP, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

### **Sec. 110.310: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

## **I. INTRODUCTION:**

The purpose of this document is to provide guidance on FDA's and CBP's strategy for enforcing and otherwise achieving compliance with the requirements of the interim final rule for submitting prior notice for food imported or offered for import into the United States (68 Fed. Reg. 58974 (Oct.10, 2003) (codified at 21 CFR 1.276 - 1.285)).

FDA's guidance documents, including this Compliance Policy Guide (CPG), do not establish legally enforceable responsibilities. Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in agency guidance documents means that something is suggested or recommended, but not required.

## **II. BACKGROUND:**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), section 307, added section 801(m) to the Federal Food, Drug, and Cosmetic Act (the Act) to require that FDA receive prior notice for food imported or offered for import into the United States. Section 801(m) also provides that if an article of food arrives at the port of arrival with inadequate prior notice (e.g., no prior notice, inaccurate prior notice, or untimely prior notice), the food is subject to refusal of admission under section 801(m)(1) of the Act and may not be delivered to the importer, owner, or consignee. If an article of food is refused under section 801(m)(1) of the Act, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

The Bioterrorism Act, section 305, also amended Chapter IV of the Act by adding section 415 to require domestic and foreign facilities that manufacture, process, pack, or hold food for consumption in the United States to register with FDA, and amended Chapter VIII of the Act by adding section 801(l) to require any food for human and animal consumption from an unregistered foreign facility that is imported or offered for import to be held at the port of entry until the foreign facility has been registered.

On October 10, 2003, FDA and CBP issued interim final regulations establishing the requirements for registration and requiring that FDA receive prior notice of the importation of food beginning on December 12, 2003 (68 FR 58994 and 68 FR 58974). For the purposes of prior notice, "food" has the meaning given in section 201(f) of the Act, and is defined as (1) articles of food or drink for man or other animals, (2) chewing gum, and (3) articles used as components of any such article, except that it does not include food contact substances or pesticides. The requirements for prior notice do not apply to:

1. Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;
2. Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States;

3. Food that is imported then exported without leaving the port of arrival until export;
4. Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.);
5. Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 et seq.);
6. Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.).
7. Prior notice also is not required under FDA requirements for food brought into the United States in a diplomatic pouch. The Vienna Convention on Diplomatic Relations (1961) provides: "The diplomatic bag shall not be opened or detained." Art. 27(3): Any baggage or cargo marked "diplomatic bag" or "diplomatic pouch" is immune from search, including by electronic devices, and thus its contents are not subject to FDA's prior notice requirements.

Information required to be submitted in a prior notice includes, with certain exceptions, the registration numbers assigned to the foreign manufacturer's and shipper's facilities that are associated with the article of food. FDA's monitoring of compliance by foreign facilities with the requirement to register under section 415 of the Act will be accomplished primarily through the prior notice review process. If an article of food is from a foreign manufacturer that is not registered as required and is imported or offered for import, then the food is subject to refusal under section 801(m)(1) of the Act for failure to provide adequate prior notice. Likewise, the failure to provide the correct registration number of the relevant foreign manufacturer, if registration is required, renders the identity of that facility incomplete for purposes of prior notice. In addition, if an article of food is imported or offered for import from any foreign facility that is not registered as required, then the food is subject to being held under section 801(l) of the Act.

In the preamble to the interim final rule, FDA stated that it planned to provide guidance to its staff regarding the agency's enforcement policies. Accordingly, this CPG describes general policies regarding the enforcement of the prior notice requirements, including the requirement to provide a required registration number.

The requirements for submitting prior notice to FDA were effective beginning December 12, 2003. During the first eight months following this effective date, FDA and CBP focused their resources on education to achieve compliance with the prior notice requirements. The agencies will continue this education and outreach, including the following:

1. FDA and CBP will distribute information flyers at the ports.
2. FDA and CBP plan to:

1. Gather data to track compliance with the prior notice requirements and to determine how best to use their resources to educate industry and the public in order to achieve full compliance.
2. Provide industry and the public with summary information about the level of compliance with the prior notice requirements, including data on the types of errors in submitted prior notices.
3. Provide the summary information on FDA's website at [www.fda.gov](http://www.fda.gov).
4. Utilize the data and summary information to assist the industry and the public in improving the submission of prior notice.

FDA may consider the failure to provide adequate prior notice as a factor in determining whether and where to examine an article of food. However, if FDA decides not to refuse an article of food under 21 CFR 1.283 or 1.285, this decision has no bearing on whether the article of food is admissible or will be granted admission under other provisions of the Act or other U.S. laws. Thus, for food that is imported or offered for import, FDA will continue its normal review, investigative, and enforcement activities for food safety and security concerns to determine whether the food is subject to refusal under section 801(a) of the Act. In addition, if FDA decides not to refuse an article of food under 21 CFR 1.283 or 1.285, this decision does not affect FDA's ability to initiate other types of actions -- such as seizures, injunctions, prosecutions, or debarments under sections 302, 303, 304, and 306 of the Act -- that may be necessary. Likewise, it does not affect CBP's ability to initiate other types of actions that may be necessary.

### **III. REGULATORY ACTION GUIDANCE:**

FDA's Prior Notice Review Center, in conjunction with CBP headquarters, should use the information below to make decisions about whether to refuse a shipment of food pursuant to 21 CFR 1.283 or 1.285 or take other actions for violations under sections 801(m) and 415 of the Act.

The following definitions and descriptions apply to this Compliance Policy Guide (CPG).

#### **A. Types of Violations**

1. Inadequate Prior Notice
  1. No Prior Notice - The article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review.
  2. Inaccurate Prior Notice - Prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the prior notice is determined to be inaccurate.
  3. Untimely Prior Notice - Prior notice has been submitted and confirmed by FDA for review, but the full time that applies under 21 CFR 1.279 for prior notice has not elapsed when the article arrives, unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response.
2. Unregistered Facility - The article of food is imported or offered for import from a foreign facility that is not registered as required.

3. No PN Confirmation

1. When a copy of the Prior Notice (PN) Confirmation is required for food carried by or otherwise accompanying an individual, but cannot be provided by the individual.
2. When the PN Confirmation Number is not affixed to an article of food that arrives by international mail.
3. When the PN Confirmation Number for an article of food for which prior notice was submitted through PNSI is not provided to CBP or FDA upon arrival.

**B. Actions in Response to Violations**

1. Education/Communication - To the extent possible:

1. Distribute information flyers at the ports to carriers and others associated with the shipment of food.
2. Provide, to the extent practicable, notice of the violation and of the prior notice and registration requirements to the person(s) who transmits and/or files the prior notice.
3. When an article of food that is carried by or otherwise accompanying an individual is not for personal use and has inadequate prior notice or the individual cannot provide FDA or CBP with a copy of the prior notice (PN) confirmation, provide the individual with an information sheet on prior notice.
4. When an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed, provide an information sheet on prior notice and forward the package to the addressee.
5. When an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper as set out below under Section C.4, provide an information sheet on prior notice to the importer, owner, consignee, or shipper.

2. Assessment of CBP Civil Monetary Penalties - CBP, in consultation with FDA, may assess civil monetary penalties for violation of 19 U.S.C. 1595a(b) against any party who aids or abets the importation of any merchandise contrary to law.

3. Refusal - FDA, in consultation with CBP, may refuse admission of an article of food under section 801(m)(1) of the Act or place it under hold under section 801(l) of the Act for violations under sections 801(m) and 415 of the Act. If an article of food is refused or placed under hold under these provisions, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA (21 CFR 1.283(a) and 1.285(a),(b)). For food that is carried by or otherwise accompanying an individual, and is refused, and if, before leaving the port, the individual does not arrange to have the food held at the port or exported, the article of food shall be destroyed (21 CFR

- 1.283(b) and 1.285(h)). For food that arrives by international mail and is refused, if there is a return address, the parcel will be returned to sender stamped "No Prior Notice - FDA Refused." If there is no return address, or if FDA determines that the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy the parcel (21 CFR 1.283(e) and 1.285(k)).
4. The phrase "the action FDA and CBP staff typically should consider taking" used in this CPG means that FDA and CBP staff, exercising enforcement discretion pursuant to their agency's policies and procedures, may take these actions or may take different or additional actions if they believe particular circumstances warrant them.

## C. Policy

This policy provides guidance to FDA and CBP staff when they encounter the prior notice situations described within this section.

The policy contains several references to Tables 1 and 2, which are set out below.

Table 1 - Requirements for the Identity of the Manufacturer (see 21 CFR 1.281)

<b>In the following circumstances</b>	<b>Provide the following information</b>
1. Any article of food, when the facility that manufactured the food <u>is required</u> to be registered.	Name, Registration Number, City, and Country of the facility that manufactured the food.
2. Any article of food, when the facility that manufactured the food <u>is not required</u> to be registered.	Name, Street Address, City, and Country of the facility that manufactured the food, as well as a reason code identifying this situation and the reason the facility is not required to be registered.
3. An article of food that is for transshipment, storage and export, or further manipulation and export.	Name, Street Address (or Registration Number in lieu of Street Address), City, and Country of the facility that manufactured the food.
4. An article of food that is sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the United States. Note: Under this circumstance, you should also refer to Section C.3. of this CPG.	Name, Registration Number (or Street Address if the facility is not required to be registered), City, and Country of the facility that manufactured the food or Name and Address of the firm that appears on the label under 21 CFR 101.5.

Table 2 - Enforcement Discretion Policy for the Identity of the Manufacturer

If, after a good faith effort, the person submitting prior notice does not know . . .	Then the person submitting prior notice should provide . . .
1. The Registration Number of the facility that manufactured the food (and the facility is <u>required</u> to be registered).	Name, Street Address, City, and Country of the facility that manufactured the food, and a reason code identifying this situation.*
2. Either the Registration Number or the name and full address of the facility that manufactured the food.	Name, Street Address, City, and Country of the headquarters of the facility that manufactured the food, and a reason code identifying this situation.*
3. The information in items 1 and 2 of this table.	Name, Street Address, City, and Country of the invoicing firm, and a reason code identifying this situation.*
<p>* Notes for Table 2:</p> <p>?? If the facility that manufactured the food is a foreign facility that is required to be registered and either its registration number is not provided or the name and address of a different facility (i.e., the manufacturing facility's headquarters or the invoicing firm) is provided, then it will be more difficult and/or may take more time for FDA and CBP to verify the identity of the manufacturing facility and its registration status and to determine whether the article of food is subject to being held under section 801(l) of the Act. As a result, if an article of food is imported or offered for import with the alternative information provided in Table 2 in lieu of the identity of the facility that manufactured the food, and if FDA has concerns that the food may pose a serious health threat, then the food may be delayed at the port of arrival until the verification is completed.</p> <p>?? As with other types of prior notice violations, FDA may consider the failure to provide required information about the facility that manufactured the food as a factor in determining whether and where to examine the article of food.</p> <p>?? We intend to reject prior notice submissions unless the prior notice includes a valid registration number <u>or</u> an appropriate reason code selected from among those provided in <u>the Prior Notice System Interface (PNSI)</u> and <u>the Automated Broker Interface of the Automated Commercial System (ABI/ACS)</u> (see Appendix 1). Rejected submissions are not confirmed for FDA review.</p>	

1. Shipments of food, other than food covered by another section of this CPG

In general, for any prior notice violation, the action FDA and CBP staff typically should consider taking is refusal and/or assessment of CBP Civil Monetary Penalties.



a. *Manufacturer.* Table 1 lists the prior notice requirements for providing information about the identity of the manufacturer for an article of food that is no longer in its natural state. If there is a prior notice violation because this information is not provided, FDA and CBP should typically consider not taking any regulatory action under the circumstances described in the first column of Table 2 if the information in the second column of that table is provided.

b. *Express Courier*

If prior notice is inadequate because it does not include the required anticipated arrival information and/or planned shipment information, FDA and CBP should typically consider not taking any regulatory action if:

- 1) The article of food is imported or offered for import via an express courier;
- 2) The person submitting prior notice is not the express courier;
- 3) The prior notice is submitted via the Prior Notice System Interface (PNSI); and
- 4) The prior notice includes the shipment's tracking number in lieu of the required anticipated arrival information and/or planned shipment information.

c. *Time Frame*

FDA and CBP should typically consider not taking any regulatory action if there is a prior notice violation because the prior notice was submitted more than 5 calendar days before the anticipated date of arrival, provided that: (1) the prior notice was submitted less than 10 calendar days before the anticipated date of arrival; and (2) the prior notice was submitted through the Prior Notice System Interface (PNSI). In addition, under the same conditions, FDA should typically provide the Prior Notice Confirmation Number when prior notice has been confirmed for review even if prior notice was submitted more than 5 calendar days before the anticipated date of arrival. Because of the way the Automated Broker Interface of the Automated Commercial System (ABI/ACS) is programmed, when prior notice is submitted through ABI/ACS, the Prior Notice Confirmation Number cannot be provided more than 5 calendar days before the anticipated date of arrival.

Please note that if any of the prior notice information, except the anticipated arrival information, the estimated quantity, or the planned shipment information, changes after FDA has confirmed the prior notice submission for review, the prior notice must be resubmitted (21 CFR 1.282(a)). The resubmission must be confirmed by FDA for review no less than 2, 4, or 8 hours before arriving at the port of arrival, with the minimum time depending on the mode of transportation (21 CFR 1.279(a)). If prior notice is resubmitted, the previous prior notice should be cancelled (21 CFR 1.282(b)).

2. Food carried by or otherwise accompanying an individual that is not for personal use

In general, the action FDA and CBP staff typically should consider taking is education/communication for minor or inadvertent prior notice violations and refusal for all other prior notice violations.

*Manufacturer.* Table 1 lists the prior notice requirements for providing information about the identity of the manufacturer for an article of food that is no longer in its natural state. If there is a prior notice violation due to the fact that this information is not provided, FDA and CBP should typically consider not taking any regulatory action under the circumstances described in the first column of Table 2 if the information in the second column of that table is provided.

3. Food imported or offered for import for non-commercial purposes with a non-commercial shipper, irrespective of the type of carrier

FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper. Generally, staff should consider a non-commercial purpose to be when the food is purchased or otherwise acquired by an individual for non-business purposes and the shipper is an individual (e.g., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for non-business purposes, i.e., not for sale, resale, barter, business use, or commercial use.)

Examples of foods imported or offered for import that may be covered by this non-commercial category are:

- ?? food in household goods, including military, civilian, governmental agency, and diplomatic transfers;
- ?? food purchased by a traveler and mailed or shipped to the traveler's U.S. address by the traveler, not the commercial establishment; and
- ?? gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment.

Note that the shipper and the carrier are different entities, and the carrier is likely to be a commercial entity even when the shipper is an individual. Thus, the food for non-commercial purposes may arrive by international mail or any other mode of transportation, but must be shipped by one individual to another individual (self, family member, or friend) to be considered for non-commercial purposes. For example, when an individual ships his or her own household goods, even when the goods are delivered to a mover or carrier for international movement, the individual is the shipper, e.g., the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States (see § 1.276(b)(12) of the

prior notice interim final rule). In another example, when an individual purchases food at Store A and sends that food to an individual by mail, the individual is the shipper and the carrier is the mail service. If the individual uses an express courier, the result is the same: the individual is the shipper and the express courier is the carrier. However, if Store A ships the food, Store A is the shipper. Since Store A is not an individual, this last example is not covered by the policy described above because the food was not imported or offered for import with a non-commercial shipper. (While a "person" sometimes can be an individual, partnership, corporation, or association, see 21 U.S.C. 321(e), by "individual" we mean a sole human being, not a partnership, corporation, or association.)

4. Food arriving by international mail that is **not** food imported or offered for import for non-commercial purposes with a non-commercial shipper

In general, the action FDA and CBP staff typically should consider taking is education/communication for minor or inadvertent prior notice violations and refusal for all other prior notice violations.

*Manufacturer.* Table 1 lists the prior notice requirements for providing information about the identity of the manufacturer for an article of food that is no longer in its natural state. If there is a prior notice violation because this information is not provided, FDA and CBP should typically consider not taking any regulatory action under the circumstances described in the first column of Table 2 if the information in the second column of that table is provided.

5. Gift Pack purchased or otherwise acquired by an individual and imported or offered for import for non-business purposes

FDA and CBP staff should typically consider not taking regulatory action if there is a prior notice violation because a single prior notice is submitted for a gift pack and the identity of the facility that packed the gift pack is submitted in lieu of the identity of the manufacturer, provided that the gift pack is purchased or otherwise acquired by an individual and imported or offered for import for non-business purposes. The person submitting the prior notice should provide the appropriate reason code, selected from among those provided in the Prior Notice System Interface (PNSI) and the Automated Broker Interface of the Automated Commercial System (ABI/ACS) (see Appendix 1).

Food is considered to be for non-business purposes when it is not for sale, resale, barter, business use, or commercial use. The policy described in this section applies irrespective of where the individual who purchased or otherwise acquired the gift pack lives and irrespective of the type of carrier. While the policy also applies irrespective of whether it involves a commercial or non-commercial shipper, please note that the guidance contained in section C.3 of this CPG applies to gift packs, and other foods, that are imported or offered for import for non-

commercial purposes with a non-commercial shipper. More information about non-commercial purposes, the difference between shippers and carriers, and the difference between commercial and non-commercial shippers is contained in section C.3 of this CPG.

For the purpose of this CPG, gift packs are considered to be food that is described with FDA Product Code 37Y--01 (human food) or FDA Product Code 72E--99 (animal food). Examples of gift packs that may be covered are:

- ?? A gift basket containing fresh fruit and/or vegetables.
- ?? A gift box containing crackers and cheeses and canned condensed soups.
- ?? A gift basket of crackers, cheeses and fresh fruit.
- ?? A wicker basket with champagne, port, scotch whisky, smoked salmon, cheese, tea, coffee, chutney, pistachio nuts, biscuits, marmalade, honey, butter biscuits, crackers, cake, mustard, olive oil, and olives.
- ?? Tote bag with infant clothing, bib, booties, and coffee and candy for the parents; or a toy dispenser with hard candy and powdered candy.
- ?? A gift bag with multiple pet food items such as rawhide chews and dog biscuits, with or without non-food items.

6. Food imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption or resale

If the article of food is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale, then FDA and CBP should follow the enforcement policies described in section C.1. of this CPG. Please note that with respect to item 1 of Table 2, there is a specific reason code for samples of food that are imported or offered for import for quality assurance, research or analysis purposes (see Appendix 1). This reason code should be used when it is applicable.

For the purpose of this CPG, samples of food are considered to be imported or offered for import for quality assurance, research or analysis purposes when they are imported in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis or is destroyed after analysis or a reasonable retention period after analysis. The analysis may include sensory analysis or evaluations such as those organoleptic analyses for testing the quality of tea or for testing for histamines. Evidence that an article of food is imported for quality assurance, research, or analysis purposes only might include, among other evidence, that the food and shipment documents are marked accordingly. The policy in this section does not apply to samples intended for test marketing, such as tasting at trade shows or product promotional tasting events.

Information about when samples are "food" for the purposes of prior notice is provided in the 2nd Edition of Guidance for Industry, Prior Notice of Imported Food, Questions and Answers, May 2004. This guidance states that, in general,

prior notice is required for samples of food, including animal feed, for research and development and test marketing (Q&A, Section C., Question 1.3). However, if the samples are items that are in such early stages of research and development that they cannot yet be considered food for the purposes of prior notice, then they would not be subject to prior notice requirements (Q&A, Section C., Question 1.3). In addition, if the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis or a sterile sample container filled with juice for heavy metal analysis, then prior notice would not apply (Q&A, Section C., Question 17.2).

#### Appendix 1: Reason Codes for Registration Number of Manufacturer Not Provided

- A. Facility is out of business
- B. Facility is private residence (21 CFR 1.227(b)(2))
- C. Facility is a restaurant (21 CFR 1.226(d); 1.227(b)(10))
- D. Facility is retail food establishment (21 CFR 1.226(c); 1.227(b) (11))
- E. Facility is non-processing fishing vessel (21 CFR 1.226(f))
- F. Facility is non-bottled drinking water collection and distribution establishment (21 CFR 1.227(b)(2))
- G. Individual gift - label name/address in lieu of registration number (21 CFR 1.281(a)(6), (b)(5), and (c)(6))
- H. Grower - satisfies farm exemption (21 CFR 1.226(b); 1.227(b)(3))
- I. Samples – quality assurance, research or analysis purposes only
- J. U.S. manufacturing facility that is not required to register
- K. Unable to determine the registration number of the manufacturer.
- L. Unable to determine identity of manufacturer - providing identity of manufacturer's headquarters
- M. Unable to determine identity of manufacturer or headquarters - providing invoicing firm's identity
- O. Gift pack for non-business purposes – providing single prior notice and identity of packer

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